

Remarks

Claims 1, 3-29 and 31-35 were pending in the subject application. By this Amendment, the applicant has amended claims 1, 3, 6, 7, and 31 and canceled claims 8-10, 17-23, 29 and 30. No new matter has been added by these amendments. Support for the amendments to the claims can be found throughout the subject application including, for example, at page 7, lines 29-30 through page 8, line 6, and in Figure 2A. Accordingly, claims 1, 3-7, 11-16, 24-28, and 31-35 are now before the Examiner for consideration.

The amendments set forth herein should not be interpreted to indicate that the applicant has agreed with, or acquiesced to, the rejections set forth in the outstanding Office Action. The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. Favorable consideration of the claims now presented, in view of the remarks and amendment set forth herein, is earnestly solicited.

As an initial matter, claims 3-10 have been objected to for improper dependent form. Specifically, claims 3-10 depend from canceled claim 2. The applicant appreciates the Examiner's careful review of the claims. By the above amendments, claims 3, 6, and 7 now properly depend from claim 1 and claims 8, 9, and 10 have been canceled. Therefore, it is respectfully requested that the objection to claim 3-10 be withdrawn.

Claims 1, 6, 7, and 29 have been rejected under 35 U.S.C. §102(b) as being anticipated by Sorenson *et al.* (U.S. Patent No. 4,099,528). The applicant respectfully traverses because Sorenson *et al.* do not disclose each and every element of the invention disclosed in the herein amended claims (See In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984)).

The claims herein have been amended to state that the arterial and venous lumens can be separated from a removable hollow hub allowing further separation of the arterial and venous lumens. Support for these amendments can be found in the specification, for example, on page 7, line 29 through page 8, line 6 where it states that "the arterial lumen **10** can be separated from the venous lumen **20** to enable removal and replacement of the arterial lumen" and, further, that the "catheter **1** of the subject invention, which includes co-axially configured, separable arterial and venous lumens, is connected to a fluid-conveying, removable, hollow hub assembly **40**." Thus, the

catheter of the subject application, which includes both an inner arterial lumen and an outer venous lumen, can be removed from the hub and the lumens further separated to facilitate replacement of either lumen, if necessary.

Conversely, Sorenson *et al.* disclose a double-lumen catheter permanently mounted to a hub, where the interior lumen is mounted within the hub and the exterior lumen is mounted upon the hub (col. 2, lines 44-50). Sorenson *et al.* do not disclose a dual catheter and hub that can be separated in order to replace one or the other lumen. Further disclosed by the Sorenson *et al.* reference is use of a tapered bushing **40** that can be temporarily interposed in the passageway at the distal opening between the interior and exterior catheters to present a smoother surface and facilitate more comfortable venipuncture. (col. 3, lines 6-19). While it is disclosed that the bushing can be removed, nowhere does Sorenson *et al.* teach that the interior and exterior catheters can be removed or replaced, but rather that they remain fixedly mounted to the hub.

As mentioned above, claim 1 has been amended to state that the arterial and venous lumens of the subject application are removably attached to a hollow hub, allowing them to be separated from the hub and subsequently from each other. Claim 29 has been canceled. Accordingly, the applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) of claims 1, and claims 6 and 7 that depend therefrom, and claim 29.

Claims 3-5, 11-16, 20-25, 27, 28, and 31-35 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Sorenson *et al.* in view of Zawacki (U.S. Patent No. 6,758,836). The applicant respectfully traverses this ground for rejection to the extent that it might be applied to the claims now presented for examination.

With regard to claims 3-5, the Office Action states that Sorenson *et al.* disclose the claimed apparatus. However, the applicant respectfully asserts that Sorenson *et al.* do not disclose the device in amended claim 1, from which these claims depend. The addition of the Zawacki reference does not cure the defects of the Sorenson *et al.* reference, which specifically teaches dual catheters mounted to a hub. While Zawacki teaches that the inner and outer lumens can terminate at different distances, it is not taught that both the inner and outer lumens are detachable from the hub.

With regard to claims 11 and 20, which depend from claim 1, the Office Action states that Sorenson *et al.* fail to disclose the particular shapes of the catheters. Claim 20 has been canceled. As regards claim 11, the applicant respectfully puts forth that the addition of Zawacki reference does not cure the failings of the Sorenson *et al.* reference, detailed above, because changing the shapes of the catheters does not necessarily render them detachable from the hub.

With regard to claim 12-14 and 21-23, the Office Action again asserts that it would have been obvious to modify Sorenson *et al.* to have different lengths between the distal ends of interior and exterior catheters. Applicant reiterates that altering the length of the catheters, as disclosed by Zawacki, does not cure the defects of the Sorenson *et al.* reference. Further, claims 21-23 have been canceled.

With regard to claim 15-16, the failings of the Sorenson *et al.* reference are detailed above. The applicant respectfully avers that utilizing lumens having tapered ends does not cure the other defects of the Sorenson *et al.* reference.

With regard to claims 24 and 25, again, the applicant reiterates that the failings of the Sorenson *et al.* reference are not cured by addition of the Zawacki teaching of lumens having a plurality of distal apertures of different cross-sectional shapes.

With regard to claim 27, the failings of the Sorenson *et al.* reference are not cured by the addition of the Zawacki reference, which teaches that catheters can be made from thermoplastics.

With regard to claim 28, the failings of the Sorenson *et al.* reference are not cured by the teachings of Zawacki that reinforcing substances can be utilized with catheters.

With regard to claim 31, the Office Action contends that Sorenson *et al.* disclose the claimed catheter and that it would have been obvious to deploy the catheter of Sorenson *et al.* in the manner disclosed by Zawacki. The applicant respectfully maintains that Sorenson *et al.* do not teach the catheter device of the subject application and the herein amended claims. To reiterate, Sorenson *et al.* teach a catheter having dual lumens mounted to a hub. The addition of the Zawacki reference does not cure the defects of Sorenson *et al.*, because Zawacki only teaches that the inner lumen is removable. Conversely, claim 31 teaches a method utilizing a catheter with dual lumens that can both be removed from a hub and further separated from each other.

With regard to claims 32, 33, 34, and 35, which depend from claim 31, Applicant respectfully asserts that the Sorenson *et al.* reference, alone or in combination with Zawacki, does not teach the claimed method utilizing a catheter with dual lumens that can be removed from a hub and separated from each other. Utilizing a guidewire or changing the location of insertion does not cure these defects of the cited references. Again, Zawacki does not teach or even suggest a catheter wherein both lumens can be removed from a hub and, further, Sorenson *et al.* specifically teaches lumens mounted to a hub, so that a bushing can be utilized in the space between them to provide a smoother surface for venipuncture.

The applicant would also like to point out that the Sorenson *et al.* catheter and bushing are specifically designed to decrease patient discomfort when being punctured with the catheter. Certainly, the Sorenson *et al.* catheter might be used with the incision method of the subject invention, but it would defeat the fundamental purpose for using the bushing and for the corresponding taper between bushing and the dual lumens.

Claim 26 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Sorenson *et al.* in view of Davey *et al.* (U.S. Patent No. 6,595,966). The Office Action asserts that Sorenson *et al.* teach the device of the subject invention except for the use of a therapeutic agent. To the extent that this rejection might be applied to the claims now presented for examination, the applicant respectfully traverses this grounds for rejection.

As discussed in detail above, Sorenson *et al.* disclose a catheter having dual lumens that are mounted in and on a hub and are, thus, not removable. Conversely, the subject application discloses a dual lumen catheter that can be detached from a hub and where the lumens can be further separated from each other. The Office Action states that Davey *et al.* disclose that a surface can be treated with heparin. The applicant respectfully asserts that the addition of Davey *et al.* does not cure the defects of the Sorenson *et al.* references. Reconsideration and withdrawal of the rejection of claim 26 under 35 U.S.C. §103(a) is respectfully requested.

Claims 8, 9, 10, 17, 18, and 19 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Sorenson *et al.* in view of Miller *et al.* and in view of Klein. These claims have been canceled from the application, thus this rejection is rendered moot.

In view of the foregoing remarks and the amendments above, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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